REMARKS

This Response is made to the Official Action mailed August 25, 2009. Claims 1 through 34 are pending in this application. The subject matter of the claims is subject to a requirement for restriction and election under 35 U.S.C. §§121 and 372. Applicants are required to make an election among six allegedly distinct inventions, listed below. Applicants respectfully traverse the requirement for restriction and request reconsideration.

Group I. Claim(s) 1-10, 23 and 24, drawn to orally dissolving film composition comprising enteric polymer, alkaline buffer and one active agent. Claims 23 and 24 are drawn to method of using the film composition of claim 1.

Group II. Claim(s) 11-17 and 22, drawn to multi-component, orally dissolving film comprising (a) first component comprising alkaline buffering, and filler, and (b) second component comprising nicotine, enteric polymer and plasticizer. Claim 22 drawn to method of using the multi-component film composition of claim 11.

Group III. Claim(s) 18-21, drawn to orally dissolving film comprising (a) first component comprising enteric polymer, alkaline buffering, and nicotine, and (b) second component comprising bioadhesive polymer. Claim 21 drawn to method of using the film composition of claim 18.

Group IV. Claim(s) 25-30, drawn oral dosage form comprising nicotine, bioadhesive material, and rapidly releasing sensory impact agent. Claims 29 and 30 are drawn to a method of using the composition of claim 25.

Group V. Claim(s) 31-32, drawn to orally dissolving film comprising cosmetic active agent and polyvinyl alcohol-polyethylene glycol graft copolymer.

Group VI. Claim(s) 33 and 34, drawn to method of making orally dissolving film.

In summary, the Action states that Group I does not require any of the specific technical features of Groups II through VI. Group II has the specific technical feature of having two components and each component has specific ingredients not required by any other Group. Group III has the specific technical feature of having two components and one of them is a bioadhesive. Group IV has the specific technical feature of having a bioadhesive and rapidly releasing sensory agent and does not require film as required by the other Groups. Group V has the specific technical feature of having a polyvinyl alcohol-polyethylene glycol graft copolymer. Group VI has the special technical feature of not requiring any specific active agent and film formed by a casting process.

Applicants respectfully traverse the requirement for restriction initially because it does not comply with the unity of invention standard set by the PCT, and secondly, because it is improper under U.S. restriction practice since there would be no additional burden upon the Examiner to search all inventions together.

The standard applicable to the instant application is not one of restriction practice under U.S. guidelines, but one of unity of invention under the PCT. In the instant case, no lack of unity of invention was found by the International Searching Authority or the International Preliminary Examining Authority, and all claims were searched and examined as one invention, indeed by the same Examiner. The question of unity of invention may be reexamined only within the scope of rules of the Patent Cooperation Treaty (35 U.S.C. §372(b)), and restriction requirements made according to U.S. practice, which are more restrictive than the PCT regulations, are in error. PCT Article 27 ("no national law shall require compliance with requirements relating to form or contents ... different from or additional to those which are provided for in this Treaty and the Regulations").

PCT Rule 13.1 states that there exists unity of invention if the international application relates "to one invention only or to a group of inventions so linked as to form a single general inventive concept." Clearly the general inventive concept which links the alleged various inventions here is the orally dissolving film composition for delivering a pharmaceutically active ingredient, in particular, nicotine. PCT Rule 13.2 states that unity of invention shall be fulfilled where there is a technical relationship among those inventions involving one or more of the same or corresponding technical features, where the technical feature defines the contribution that each of the claimed inventions makes over the prior art. The special technical features shared by each of the Groups which the Examiner has deemed distinct are (i) the orally dissolving film composition, and (ii) the common ingredients that make of the inventive orally

dissolving film composition. Since the various compositions are related to the same underlying technical features, there is unity of invention and a restriction requirement is improper.

Furthermore, in accordance with U.S. practice, M.P.E.P. §803 mandates two criteria for a proper restriction requirement: 1) the inventions must be independent or distinct as claimed; and 2) there must be a serious burden on the Examiner if restriction is not required.

It is urged that the above Groups are of a single inventive concept for which a single patent should issue and do not constitute distinct inventions such as to require that the subject matter be prosecuted in separate patent applications. "Independent", according to M.P.E.P. §802.01, means that "there is no disclosed relationship between the subjects disclosed." The subject matter of Groups I and VI is clearly related, having arisen from a singular research effort, as related to novel orally dissolving film compositions for administering a pharmaceutically active agent. Applicants urge that in order to be a proper restriction requirement, there must be a serious burden on the Examiner if restriction is not required. It does not appear that this criterion is met with the restriction requirement made herein.

Accordingly, in view of the foregoing and further in view of the interest of efficiency and cost savings to both Applicants and the PTO, reconsideration and withdrawal of the requirement for restriction are requested. However, pursuant to 37 C.F.R. §§1.142 and 1.143, Applicants provisionally elect, subject to the traverse set forth above, Group I, covering claims claim(s) 1-10, 23 and 24, drawn to orally dissolving film composition comprising enteric polymer, alkaline buffer and one active agent, and a method of using the film composition. Should the restriction become final, Applicants reserve the right to prosecute, in one or more patent applications, the cancelled claims, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification.

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In view of the above remarks, reconsideration of this application is requested. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

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